Medical Coverage Policy

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Helicobacter Pylori Serology Testing

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses serology testing in the adult and pediatric populations for Helicobacter pylori infection which is associated with peptic ulcer disease and gastric cancer.

Coverage Policy

Serology/antibody testing (CPT code 86677) for diagnosing Helicobacter pylori is considered experimental, investigational and unproven for ANY indication including making a diagnosis of a Helicobacter pylori infection.

Health Equity Considerations

It is estimated that approximately 13–81% of people have an infection with H. pylori and prevalence varies with age, region, race, and socioeconomic class (Best, et al., 2018). In a 2022 systematic review and retrospective study on racial disparities on H. pylori infection in the United States, Brown et al. found that Blacks and Hispanics had a higher infection prevalence rate compared to whites. The ratio of Black to white infection prevalence ranged from 1.3 to 5.4 and Hispanic to white ranged from 1.8 to 4.4. Compared to whites, Blacks were found to have 2.6–4.4 increased odds of having an infection and Hispanics were found to have 1.8–3.9 increased odds of having an infection. According to the authors, this study points to a need for better understanding of the racial differences in H. pylori infection prevalence which may lead to improved risk stratification strategies for gastric cancer prevention.

General Background

Helicobacter pylori (H. pylori) is a key causal factor in most peptic ulcer disease and a primary risk factor for gastric cancer. The pathogenic role of H. pylori in peptic ulcer disease, both duodenal and gastric, is well recognized. Nearly 95% of patients with duodenal ulcers and 80% of patients with gastric ulcers are found to be infected with H. pylori. Treatment for H. pylori infection includes varied combinations of antibiotics, proton pump inhibitors (PPIs), histamine H2 receptor antagonists and bismuth compounds. Eradication of H. pylori significantly lowers the recurrence rate of H. pylori-associated peptic ulcers.

H. Pylori Testing Methods

H. pylori infection can be confirmed by invasive or noninvasive methods. Invasive tests require upper esophagogastroduodenal (EGD) endoscopy, which is considered the reference method of diagnosis. During endoscopy, biopsy specimens of the stomach and duodenum are obtained, and the diagnosis of H. pylori can be made by rapid urease testing (RUT), histology and/or culture. If possible, noninvasive testing is done before tissue testing. Noninvasive methods include urea breath testing (UBT), stool antigen testing (e.g. H. pylori stool antigen [HpSA]) and serology. The clinical utility of these testing methods lies in their ability to accurately identify H. pylori infection, which allows for subsequent treatment and eradication. Urea breath testing has been proven to be a safe and effective test for identifying the presence of H. pylori with a reported sensitivity of 94.7% and specificity 95.7% (Vakil and Fendrick, 2005). The accuracy of UBT is comparable to

endoscopic biopsy (Islam, et al., 2005; Perri, et al., 2005). Sensitivity and specificity ranges of 90%–93% and 91%–100% respectively, have been reported for stool antigen testing (Canadian Agency for Drugs and Technologies in Health [CADTH], 2015).

Best et al. (2018) conducted a Cochrane systematic review of the literature to compare the diagnostic accuracy of non-invasive H. pylori testing in symptomatic and non-symptomatic people. The diagnostic tests included urea breath testing, serology and stool antigen testing. A total of 101 prospective and retrospective studies met inclusion criteria. Of the 11,003 subjects, 5839 had H pylori. The studies evaluated the tests when done alone or in combination. A total of 34 studies (n=4242) evaluated serology; 29 studies (n=2988) evaluated stool antigen test; 34 studies (n=3139) evaluated urea breath test-13C; 21 studies (n=1810) evaluated urea breath test-14C; and two studies (n=127) evaluated urea breath test. There was a statistically significant difference in the diagnostic accuracy between urea breath test-13C, urea breath test 14C, serology and stool antigen test (p=0.024). Specificity of urea breath test-13C, 14C, serology and stool antigen test was 0.94, 0.92, 0.84 and 0.83 respectively. The author's concluded that in symptomatic populations with no history of gastrectomy, and no recent use of proton pump inhibitors or antibiotics, urea breath tests had a high diagnostic accuracy, whereas serology and stool antigen tests had lower accuracy to diagnose H. pylori. The thresholds used for these tests were highly variable and the authors were unable to identify specific thresholds that might be useful in clinical practice. There is a need for additional high-quality studies to assess the accuracy of non-invasive tests for H. pylori.

Serological assays measure specific H. pylori immunoglobulin G (IgG) antibodies that determine if an individual has been infected. Serological testing has been the mainstay of H. pylori diagnosis, particularly in primary care, due to the accessibility, rapid results, and low cost of this testing method. However, some serological tests have not been locally validated and therefore have suboptimal sensitivity and specificity in practice. The value of noninvasive H. pylori testing is also related to the background prevalence of H. pylori infection. False positives are more likely to occur in areas where H. pylori infections are less prevalent (Talley, et al., 2005a). Serological tests are also unreliable indicators of H. pylori status in patients who have received treatment for the infection. Because it cannot distinguish between current and past infection, serological testing has poor accuracy in settings of low and intermediate H. pylori prevalence, limiting its value in the United States (Vakil and Fendrick, 2005).

Serology testing for H. pylori pre-dates UBT and stool antigen testing and has been reported to have decreased accuracy based on local validation with a wider sensitivity and specificity range of 80–95%. Since the positive predictive value of antibody testing is influenced by the prevalence of an infection, the PPV in areas of low prevalence such as much of the United States is poor. A positive test has little value in predicting the actual presence of an active infection. False positives lead to inappropriate treatment, as well as lack of treatment response and encouragement of antibiotic resistance (Vakil and Fendrick, 2005). The low accuracy of serology testing results in the need for additional confirmatory non-invasive (i.e., UBT, stool antigen), or invasive (i.e., endoscopy/biopsy) testing. Therefore the performance and clinical utility of this testing method compared to other non-invasive methods is lacking.

Professional Societies/Organizations

American College of Gastroenterology (ACG): According to the ACG practice guidelines for the management of H. pylori infection, antibody testing (e.g., serum, whole blood, urine) is widely available but has poor positive predictive value in populations with a low prevalence of H. pylori infection, limiting its usefulness in clinical practice. Antibody testing is of limited benefit in documenting eradication of H. pylori, as results can remain positive years after successful cure of the infection (Chey, et al., 2007). Testing to prove H. pylori eradication should be performed using a urea breath test, fecal antigen test or biopsy-based testing at least four weeks after the

completion of antibiotic therapy and 1–2 weeks after PPI therapy has been withheld. The ACG noted that "because of the higher pretest probability of infection, patients with documented PUD represent a rare group, where it is acceptable to utilize an IgG H. pylori antibody test." In most other scenarios in which the pretest probability of infection is lower, tests which identify active disease are preferred over antibody testing (Chey, et al., 2017).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
86677	Antibody; Helicobacter pylori

ICD-10-CM Diagnosis Codes	Description
	All codes

***Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	No clinical policy statement changes.	5/15/2024

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